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EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,053	FRIDDLE ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The amendment filed 3-9-04 has been entered into the record and has been fully considered.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

3. As a result of Applicant's amendment, all rejections not reiterated herein are withdrawn.

4. Claims 13-15 are newly submitted. Claims 1 and 4-15 are pending.

Election/Restriction

5. Applicant's election with traverse of Group I, now claims 1 and 4-15 to the extent of SEQ ID NO:4 in the Paper of 9-3-03 is acknowledged. The traversal is on the ground(s) that Group I and III are related. Subsequent search by the Examiner has revealed that SEQ ID NO:6 is linking to invention I in that SEQ ID NO:6 is completely encompassed by SEQ ID NO:4. Groups I and III are thus rejoined as to the linking structure of SEQ ID NO:6. Restriction of Group II (SEQ ID NO's:1-2) is maintained in that the structures are uncommon to SEQ ID NO's:4 and 6.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1 and 4-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, credible asserted utility or

a well established utility.

The specification discloses that the claimed invention is related to isolated novel human proteins (NHP's) and contemplates the use of the disclosed nucleic acids for example in the, "generation of antibodies, as reagents in diagnostic assays, for the identification of other cellular gene products related to the NHP's, as reagents in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological or medical disorders and diseases such as but not limited to cardiovascular disease, hyperproliferative disorders, stenosis (or preventing restenosis) and connective tissue disorders," see in particular pp. 21, lines 18-28. Similarly related uses are disclosed throughout pp. 1-33 including for preparation of probes and primers for use in hybridizations, for production of proteins and mRNAs encoded by said genes and related nucleic acids. Also contemplated are uses for the various reagents related to the NHP molecules including nucleic acids, peptides and antibodies.

However, such utilities as disclosed do not appear to be either specific or substantial because these uses merely rely on the inherent properties of any nucleic acid to hybridize (bind) and encode. There is no specific information provided as to the use and/or function that is specific to the sequences of SEQ ID NO:4 and 6. The peptide is not exemplified as providing any particularly useful information, activity or function and the nucleic acids are not disclosed as indicative, prognostic or diagnostic to any particular condition such that the sequence reveals useful information to the artisan as to it's presence, absence or particular significance. The peptide is merely identified

as a member of one of the broad genus of newly isolated human peptides and encoding nucleic acids for which no particularly useful information is provided as to how the artisan may specifically utilize the sequence to obtain immediate benefit and/or significance.

Accordingly, the disclosed nucleic acids merely constitute research reagents for further experimentation to discover the "real-world" significance or use of the nucleic acids claimed. The recited uses also do not constitute a well-established utility because the utility of the sequence is not established within the art. For these reasons there does not appear to be either a specific and substantial asserted utility or well-established utility for the claimed nucleic acids.

Applicants argue in the response of 3-9-04 at p. 4-first paragraph p. 5, that in accordance with the Revised Interim Utility Guidelines (Exhibit A) utility is established as the noted sequence shares nearly 100% identity with recently issued US Patent 6,656,707 (alignments Exhibits B-D).

These arguments have been fully considered but are not persuasive. Applicant's reference to Patent No. 6,656,707 as establishing patentable utility for the claimed sequence is not persuasive because each application is examined on its own merits. In the decision of *In re Hutchison*, 69 USPQ 138 (CCPA, 1946), the court held that "We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the six article claims on appeal were properly rejected below, and this we pass upon without further reference to, and without comparing them with, the claims in the patent or the claims which stand

allowed in this application." In essence, the position that each application is examined on its own merits can be found in the judicial precedent cited above. The rejections in the instant application will only be withdrawn if they are shown to be legally unsound. Nevertheless, the Examiner notes that while the time of the invention in the '707 patent is apparently before Applicant's, Applicant's specification provides no similar teachings that would indicate contemplation of the instantly claimed sequences as C3B/C4B complement receptor-like molecules. Therefore, rejection on these grounds is maintained.

Applicants further argue within the second paragraph at p. 5-first paragraph at p. 7 of the 3-9-04 response, that a number of additional substantial and credible utilities are provided, not the least of which is in forensic biology (specification p. 3, line 12, p. 17, line 1-p. 19, line 16. Applicants note the case law of, *Raytheon v. Roper*, *In re Malachowski* and *Hoffman v. Klaus* with arguments that only one credible assertion of utiltity is required to meet the requirements of 35 USC 101. In particular, Applicants note single point mutations (nucleotide polymorphisms) for the nucleic acids of the invention. Applicants argue that "as such polymorphisms are the basis for forensic analysis, which is undoubtedly a "real world" utility, the presently claimed sequence must in itself be useful."

These arguments have been fully considered but are not persuasive. As noted in the grounds of the rejection, to overcome the utility requirement the invention must provide at least one specific and substantial, credible asserted utility or a well established utility. Credibility is not a requirement alone, the utility must also be specific

and substantial. However, the rejection of record is not based upon a lack of credibility. While the Examiner agrees that SNPs may be used in genetics testing, see for example Carey et al., Electrophoresis 2002 May, 23 (10):1386-97, Gray et al., Human Molecular Genetics, 9(16):2403-2408, 2000, and Chakraborty, Electrophoresis 1999, 20:1682-96, the Examiner does not recognize that the mere identification of any SNP provides for specific and substantial utility in forensic testing. This asserted utility appears to merely rely on the placement of the instantly identified SNPs within the broad generic class of any identified SNP and says nothing of its particular relation to any individual genome, genetic population or genetic condition. As noted in Carey et al, Introduction pp. 1386-87, short tandem repeat (STR), and variable number of tandem repeat (VNTR) analysis (using restriction fragment length polymorphism (RFLP) segments) are the standard in genetics testing. In particular, Chakraborty details controlled genetic analyses based upon 13 scientifically established STR markers. Chakraborty notes that only more recently have single nucleotide polymorphisms become a focus in forensics/genetics testing. As noted in Chakraborty et al., p. 1692, column 1, lines 34-42 what is required for accurate SNP analyses are the, "specific details of the population genetic properties of the SNP loci (e.g. their genomic location, allele frequency distribution, and the extent to which they depict the effect of a genetic substructure in the populations), for which data are still lacking." Yet none of these factors are provided for the claimed sequences. Chakrabarty depicts a detailed study in comparison with known STR markers and concludes that data on more than a single locus is required, in particular for reasonable certainty under different conditions as noted at pp. 1692-93 more than 81

amount of correlative teachings are required for genetics testing and determination. For example SNP markers are useful in association once there is an identified functional consequence with a disease trait or when an SNP is properly identified as a marker in linkage disequilibrium, see in particular Gray pp. 2404. Identification of the SNP is required. However, the artisan must also be equipped with SNP frequencies across the human genome, a suitable number of SNP markers required for a linkage disequilibrium scan, proper genotyping methods, correlative teachings between phenotype and genotype, information on genetic recombination events including hotspots, and a sufficient number of SNPs to allow for forensics, paternity or genetic determination amongst a population. Significance is established only upon discovery of how any assays specific results lead to meaningful analysis, i.e, identification of a particular end result and its relation to predicting paternity, disease, biological function or some form of indicia with significance. The assays are not specific and substantial to the claimed sequences until their prevalence, outcome or function is known to correspond to a specific end result, function or significance. In the absence of such specific information, the SNP analyses are merely based on their inherent prevalence within the genome as a whole. While the sequences may serve as a basis for future research and provide potential for use in such testing, using the identified sequence, at this juncture is experimental in that there is no data or evidence of record that indicates the SNPs as disclosed are determine prevalence, paternity or forensic source as required. Therefore, rejection on these grounds is maintained.

At the paragraph spanning p. 8-9 Applicants point out that not all nucleic acids

loci may be needed. Thus, there is no recognized forensics potential based upon Applicants disclosure of single SNPs without knowledge of the population genetic properties of the SNP loci. Moreover, even full description of the loci would not be enough as more than a single loci is required for accurate statistical analyses. Thus, rejection on these grounds is maintained.

Applicants further argue at p. 7, paragraph 2-p.8 paragraph 1 that indicia of prognostic or diagnostic use related to a particular disease is not the standard of utility within *In re Brana* and that forensic analysis does not require a relationship with a specific medical condition to be useful in forensics, i.e., to distinguish individual members amongst a population. Applicants argue that this is not a case of potential utility in that the polymorphic markers are in worst case scenario at least useful to distinguish amongst at least 50% of the population, that this use is definitely "real world" and that a patent need not disclose that well known in the art as in *In re Wands*.

These arguments have been fully considered but are not persuasive. SNPs alone, without more, are insufficient for immediate use in forensic biology analysis, see in particular Gray, Chakraborty and Carey as noted above. The specification fails to exemplify how the claimed sequences distinguish amongst any population as a whole and fails to provide relevant data required to determine genetic prevalence, including for example penetrance, variability and distribution of the allele and/or polymorphic frequencies, see in particular Gray and Chakraborty et al., as above. While Applicants assert that the SNP markers would be useful to distinguish at least 50% of the population, the Examiner notes that no such evidence is of record. What is missing is a

description regarding the penetrance or proportion of individuals in the general population that possess one of the identified polymorphisms from the other. In fact multiple polymorphisms appear to be established for this genetic allele as multiple SNPs are delineated within pps. 17-19 of the specification. On this basis alone, it would appear that no single SNP could possibly distinguish amongst at least 50% of the population. This would be possible if only 2 different polymorphisms were present in the population, yet here there are several noted and no information on the allelic frequencies are noted. Thus, the Examiner disagrees with the conclusion that instant sequences can be used to distinguish 50% of the population and find no evidence that such fact is well known. As supported by Chakraborty and Gray, rejection on these grounds is maintained. No specific data for foresnics analysis of the claimed sequences is provided.

Applicants argue at p. 8, second paragraph that polymorphisms are the basis of and critical to forensic genetic analyses and that clearly this use is substantial and real world.

These arguments have been fully considered but are not grounds for withdrawal of the rejection. It is true as noted in Chakraborty and Gray above that polymorphisms are used in genetic analysis testing. However, this use is substantial only once the genetic analysis testing actually distinguishes a population, parent or individual amongst others. Applicants have not shown how their sequences are capable of such differentiation and have not provided sufficient frequencies or other data to allow such determination amongst a population. As Chakraborty and Gray note, a substantial

contain polymorphic markers and that even though most genes provide for polymorphisms, such is not useful until the polymorphic markers are identified. Applicants assert that the Examiner is confusing specific utility for unique utility and that such is improper as supported by *Zeiss v. Renishaw* in that an invention does not need to be the best or only way to accomplish a certain result. Applicants argue that the only relevant question in regard to meeting the requirements of 35 USC 101 is whether every nucleic acid can be so used and that the clear answer to this question is an emphatic no. Here Applicants appear to assert that because not every nucleic acid is useful in forensics that the utility of instant sequences asserted to be useful in forensics places it within the category of having specific, substantial and credible utility with respect to the statute.

These arguments have been fully considered but are not persuasive. The Examiner has not rejected the instant sequences for not being unique. The Examiner maintains that the mere description of the polynucleotides noted to exhibit single nucleotide polymorphisms fails to place the artisan with a specific and substantial utility, including for the asserted use in forensics analysis. No evidence of record demonstrates that instant sequences are useful in forensic biology or paternity testing. As applicants allude, not every sequence and indeed not every SNP is recognized as providing for utility. Applicants have not provided evidence or arguments that would distinguish how their sequences are useful in forensics while others are not. What is missing from the specification is those teachings that demonstrate that the claimed sequences can be used in forensics or paternity testing to distinguish amongst

individuals within a population. In particular there are no specifics as to the polymorphic traits, their linkage, prevalence, distribution or frequencies that would aid in forensics determination. Applicants fail to provide such specifics. Further, the Examiner is unaware of any case law or line of reasoning that would indicate that because not every nucleic acid is useful in forensics testing that instant SNPs are. Therefore, rejection on these grounds is maintained.

Applicants argue in the paragraph spanning pp. 9-10 that the Examiner is questioning the utility of forensics as being not established in the art and that *In re Brana* supports utility of the invention because the described polymorphisms are within a broad family of polymorphisms for which utility is well established.

This argument has been fully considered but it is not persuasive. The Examiner fully recognizes the use of forensics for example in paternity testing. However, the utility of instant sequences is not well established in the art for forensics determination, paternity testing or to distinguish any particular population amongst others. The fact that other DNA sequences and particular SNPs have been used in forensics testing is not based upon any common or shared principle with instant sequences. Indeed the utility of individual SNPs appears to lie in their unique distribution patterns which vary for each SNP and amongst individuals of a population. Thus in contrast to Applicants analysis, utility for any one SNP fails to provide utility to any other. There is no evidence or exemplification of the instant SNPs utility in distinguishing amongst populations and as noted in Gray, distribution frequencies or particular linkage analyses required for the instant sequences are not disclosed. The decision of *In re Brana* is

relevant here but only to the extent that their findings were contrary to utility in a class of molecules for which predictability of function was not provided. There is no teaching that would indicate that every SNP would automatically be useful to provide for paternity testing or forensics determination. Indeed, as Applicants stipulate, not all sequences are useful in forensics testing but Applicants fail to delineate how their particular sequences are. Therefore, rejection on these grounds is maintained.

At pages 10-12 of the 3-9-04 response Applicants argue under *In re Brana*, *In re Angstadt and Griffin*, *Amgen v. Chugai*, *In re Wands*, *In re Langer* and *In re Marzochi* that utility or usefulness necessarily includes the expectation of further research and development and that the wide use of polymorphisms such as those described by Applicants in forensic analysis every day strongly argues against such a use requiring "undue experimentation".

These arguments have been fully considered but are not persuasive. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. '101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to specific nucleic acid sequences that have been shown to exhibit single nucleotide polymorphisms. However, the significance, function or indicia of the sequences or SNPs within the broad class of all genetic sequences or SNPs is yet to be determined. Accordingly, the function or biological significance of the molecule remains to be discovered. There is no evidence of record or any scientific line of reasoning that would support a conclusion that the sequences were, as of the filing date, useful for diagnosis, prevention and/or treatment or that the polymorphisms were specifically useful amongst any other polymorphic sequences for forensic analysis, DNA testing and methods of screening for drugs. Until some actual and specific significance can be attributed to the protein, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. As noted by Chakraborty and Gray above, more than the mere SNP sequence is required. Population genetics demands further identification of allele frequencies and distributions amongst different populations as well as information about particular polymorphisms, repeat regions, lengths and relative positions within normal and aberrant chromosomes. Without such guidance the artisan cannot provide for meaningful comparison and utility in forensics testing is not provided. In instant case, only particular polymorphisms amongst an isolated sequence are provided

without information as to the gene or allele it relates to, its distribution amongst individuals and its frequencies within the population. Therefore, rejection on these grounds is maintained.

At pp. 12, second paragraph-14 of the 3-9-04 response, Applicants argue that the invention provides the utility of tracking expression of the claimed sequence as noted at p. 6, lines 4-6 of the specification and that the sequences are a specific marker of human chromosome 9, a target for the discovery of drugs that are associated with human disease, and have utility in DNA "gene chip" methodology. Applicants argue that their sequences enhance the utility of the DNA chips and that such methods are recognized (well established) as being patentable, "real world" and substantial in that there is value in the industry and such methodologies are the subject of issued US Patents. Applicants further argue that the sequences provide specific utility in that the nucleotides are expressed. Applicants provide Exhibits E-L in support of their arguments.

These arguments have been fully considered but are not persuasive. Tracking expression of the noted sequences or the location of their genetic components on the chromosome are not deemed to be specific and substantial or well established utilities because expression or locale lends nothing to the description of the significance of the sequence, what it does and how it may be used. All sequences of the genome may be mapped to a particular locale on the chromosome but utility is not established until the marker is identified within the context of the genome as useful in for example forensics testing, paternity analysis or linkage studies as related to specific disease or condition.

No such evidence is now of record that pertains specifically to the isolated sequences and a condition or indicia that provides for meaningful significance or use. Exhibits E-J are noted to show other issued US Patents. However, as noted above each patent is examined on its own merits and no further comments are deemed necessary as to the relevance of the data provided therein. While Applicants note Exhibits K and L, the Venter and Jasny references were not provided to the Examiner or properly made of record for consideration. Thus, further comment with respect to the reference teachings cannot be provided. While a DNA chip may provide a means for screening DNA samples, a nucleic acid is not deemed to have utility merely because it can be placed upon such a chip and put through various experimental paradigms. Mere expression or identification of the locale of a gene on the genome is not recognized as providing for specific and substantial or well established utility. Such appears to be an assertion based upon a broad class of expressed and encoding nucleic acids for which no specific and substantial use is immediately recognized amongst the broad class. The completion of such invention would rely upon further experimentation for example to discover what diseases similarly mapped to the locale or what types of expression correlate to a particular condition. Therefore rejection on these grounds is maintained.

The biological role of a polynucleotide or encoded protein is not required to render a gene chip marketable and is currently being exploited by a number of companies to determine correlations between expression patterns of nucleic acids and diseases. A gene chip is a customized device in biomedicine that allows researchers to detect, simultaneously, the presence and activity patterns of tens of thousands of DNA

sequences. A gene chip can be used by researchers to describe the genetic malfunction associated with a disease, detect the presence of the disease in a particular patient, calculate a patient's genetic predisposition to that disease or identify the medicines likely to be most effective in treating a particular patient with the disease. However, a correlation is required between altered expression of a nucleic acid and a particular disease or disorder; otherwise further experimentation is required to determine what genes are altered in which diseases. Even if the expression of Applicant's individual polynucleotides are affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed polynucleotides have no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what use any expression information regarding this polynucleotide could be put. There is no doubt that gene chips are valuable tools in studies of gene expression and for drug discovery. However, the instantly claimed nucleic acid molecules, their expression and/or locale are not disclosed as being associated with any particular disease or condition. Rejection on these grounds is maintained.

Additionally, at pg 13-15 of the 3-9-04 response, Applicant argues that the Examiner has confused the requirement for a specific utility with an alleged need for a "unique" utility. Applicant argues that instant sequences have greater utility than other genetic sequences in that they are expressed and are specific to chromosome 9 Applicants assert utilities for identification of protein coding sequences, mapping a

unique gene to a particular chromosome, and identifying splice junctions or intron/exon boundaries . Applicants argue citing case law, that the fact that other expressed sequences could be used to track gene expression, map protein coding regions or this specific region of chromosome 9, does not mean that the uses of the present sequences are not specific utilities. Appellant cites Carl Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991) which sets forth that "an invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications". However, Carl Zeiss is inapposite to the facts of the instant case.

In Carl Zeiss, the district court had found that a claim to a probe containing a stylus which is mounted to a movable arm above a table which supports an object to be measured lacked utility because "the arbitrary presentation of part of an invention does not constitute a claim of a valid invention" and that the claimed device could not function as a probe. See Carl Zeiss at 1180. In the instant case, the claims lack utility not because they are incomplete, and not because they do not set forth the best or only way to accomplish a result, and not because they are not unique, but because they do not have either a well-established utility or a specific and substantial asserted utility. Applicants mischaracterize the Examiner's position regarding the requirements for utility. There is no dispute on the case law itself. The issue at dispute is what constitutes a specific and substantial utility.

A specific utility is a utility specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. To

satisfy the utility requirement under 35 U.S.C. § 101, a utility does not need to be unique; however, it must be specific and substantial. The use of the present nucleic acids in tracking gene expression patterns on a gene chip merely relies on its placement within the broad generic class of any expressed nucleic acid. It is not specific and substantial to the claimed sequence, because such a use would be applicable to any expressed sequence and alone lends no significance to the detection of expression. Further, it is noted that Applicant fails to specifically disclose the significance of using of the present nucleic acid sequences in mapping the protein coding regions to chromosome 9. Again, the fact that the sequences are derived from genomic DNA places the sequence within the broad generic class of known genomic sequence but says nothing of its significance and how the sequence may be used to provide for immediate benefit to the public. While the sequence may be mapped or its expression detected, its significance is undisclosed. Such uses constitute a wish to know basis for further research to identify a particular function or significance of the claimed sequences, their expression, aberration or locale as related to any particular condition and without such detail are not specific and substantial utilities so as to provide immediate benefit to the public. The relationship amongst instant cDNAs and the genomic background is not provided or disclosed. Thus, rejection on these grounds is maintained.

At pp. 15-16 of the 3-9-04 response, Applicants note the case law of *Juicy Whip Inc. v. Orange Bang Inc.*, *Brooktree Corp. v. Advanced MicroDevices* and *State Street Bank & Trust Co. v. Signature Financial Group Inc.* In addition, Applicants argue that

the MPEP and Utility Guidelines are not judicial precedent. Applicants argue that review of various issued US Patents with no "real-world" utility support that the Examiner is holding Applicants to a different standard and that rejection therefore cannot be maintained.

These arguments have been fully considered but are not persuasive. While the Examiner does not dispute judicial precedent, examination is provided under USPTO regulations as provided within the MPEP. While each Patent is examined on its own merits, the facts of instant case are unique to those noted. Review by the Examiner of the rejection of record and Applicants arguments has been fully considered but is not found to be persuasive. There is no apparent legally sound reasoning based upon judicial precedent nor any grounds based upon scientific reasoning that would substantiate a finding that Applicants disclosure of instantly claimed sequences noted to be single nucleotide polymorphisms, provides for the requirements under 35 USC 101. Thus, rejection based upon the aforementioned grounds is maintained.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 and 4-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth

above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants argue in the response of 3-9-04 that as the invention is provided with utility as argued above, that the rejection on this basis under 35 USC 112, first paragraph cannot stand.

Applicants arguments filed 3-9-04 have been fully considered but are not persuasive for the reasons set forth above. Utility for the claimed invention has not been established within 35 USC 101 and 112, first paragraph and therefore rejection on these grounds is maintained.

Status of Claims

10. No claims are allowed.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.

Sharon L. Turner, Ph.D.
June 7, 2004